

REMARKS

Entry of the foregoing and favorable consideration of the subject application, in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

The Office Action Summary correctly indicates that claim 1 is under consideration and stands rejected.

By the present amendment, claim 1 has been amended to recite the claimed subject matter more concisely without altering the meaning or scope of the claim by deleting redundant recitation of the adjective “first” of “first intron” and the parenthetical “(intron 1).” The deleted language was redundant and superfluous, because the intron of the 5’ non-translated region of a plant H3.3 histone gene is equivalently described as the first intron of a plant H3.3 histone gene, and has also been designated intron 1.

By the present amendment, the first paragraph of the specification, which was added to the specification by amendment requested in the Transmittal Letter filed with the Application on December 21, 2001, is amended to reflect the current status of a non-provisional parent application as requested by the Office.

No new matter is introduced by means of the foregoing amendment. Applicant reserves the right to file a divisional or continuation application directed to any subject matter that may have been canceled in the prosecution of this application.

Priority

The Office has acknowledged that the present application appears to claim subject matter disclosed in prior Application No. 09/000,062, filed May 29, 1998, and PCT/FR96/01109, filed July 17, 1996.

A reference to the prior applications was inserted before the first sentence of the specification by amendment requested in the Transmittal Letter filed with the Application on December 21, 2001. By the present amendment, this first paragraph of the specification is amended to reflect that U.S. Application No. 09/000,062, filed on May 29, 1998, is now U.S. Patent No. 6,338,961.

Rejection under 35 U.S.C. § 112, second paragraph

Claim 1 has been rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Office has inquired about the frame of reference with regard to the recitation of "the first intron." The rejection is respectfully traversed. It is submitted that one skilled in the art would understand the meets and bounds of the claimed invention.

One skilled in the art would understand that what is meant by "first intron" is the first intron of a plant H3.3 histone gene. The first intron of the plant H3.3 histone gene is located in the 5'-non-translated region, and is the only intron in the 5'-non-translated region of the plant H3.3 histone gene. Thus, claim 1 refers to the only intron located in the 5'-non-translated region of a plant H3.3 histone gene, which is also accurately designated the first intron of the plant H3.3 histone gene, and may be accordingly also designated intron 1 of said gene.

Without agreeing with the alleged basis of the rejection, claim 1 has been amended to recite the claimed subject matter more concisely by deleting the redundant recitation of the adjective "first" of "first intron" and the parenthetical "(intron 1)." Claim 1 particularly points out and distinctly claims the subject matter which Applicants regard as the invention in

a manner which one skilled in the art would clearly understand. Accordingly, withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 112, first paragraph, written description

Claim 1 has been rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that applicants had possession of the claimed invention at the time the application was filed.

The Office relies upon *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) (hereinafter “*Eli Lilly*”) to support the rejection. The Office alleges that “[o]nly Applicant’s specific SE ID NOS 1-7 are disclosed.” However, the Office has recognized that *Eli Lilly* does not require that claims be limited to the examples disclosed in a specification. “Describing the complete chemical structure, i.e., the DNA sequence, of a claimed DNA is one method of satisfying the written description requirement, but it is not the only method. See *Eli Lilly*, 119 F.3d at 1566, 43 USPQ2d at 1404. Therefore, there is no basis for a per se rule requiring disclosure of complete DNA sequences or limiting DNA claims to only the sequence disclosed.” See, e.g., Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, paragraph 1, “Written Description” Requirement, 66 Fed. Reg. 1099, 1101 (Jan. 5, 2001)(internal quotation omitted)(hereinafter referred to as the “Written Description Guidelines”).

Applicants respectfully submit that the intron recited in claim 1 as amended, is described in the specification by reference to representative species described therein taken together with examples of how to make and use the claimed invention and the knowledge in the art. Indeed, in Example 2, parts (2) and (3), two different representative histone H3.3

genes cloned from *Arabidopsis* are exemplified and, in particular, the intron isolated from the 5'-non-translated region of each gene is described. A single large intron is known to be located in this region in histone H3.3 genes as substantiated by Chaubet et al. (1992, *J. Mol. Biol.*, 225:569-574), which is referenced in the Examples of the specification.

Additional specific structural features include the consensus sequences of the 5' and 3'-splice sites of those introns. Such consensus sequences are common to all introns and are known to the skilled person. *See, e.g.*, Sinibaldi et al., 1992, *PNAS*, 42:229-57 (cited by the Office). Taking the description of the specification, and representative species exemplified in the Examples, together with the knowledge in the art, the skilled person would understand substantial structural features of the recited intron of the 5'-non-translated region of a plant H3.3 histone gene.

"The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice . . . or by disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus." *Written Description Guidelines*, 66 Fed. Reg. at 1106. The Office has recognized that in some circumstances, even one species can adequately support a genus. *Id.* In the present application, the actual reduction to practice of a plurality of species is disclosed. Applicants respectfully submit that the description of the identity, source, and a method of identification and isolation together with examples thereof provide the requisite description when taken together with knowledge in the art of common structural features of intron sequences.

For at least the foregoing reasons, which are further supported by the following discussion directed to enablement, withdrawal of the rejection under 35 U.S.C. § 112, specifically the first paragraph written description requirement, is appropriate and is respectfully requested.

Rejection under 35 U.S.C. § 112, first paragraph, enablement

Claim 1 has been rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. The rejection is respectfully traversed.

The Office purports to rely upon an analysis of the, so called, *Wands* factors to allege that undue experimentation would be required to isolate the claimed sequences. However, the Office is not correct in its analysis of the state of the art and the amount of unpredictability in the art, particularly with respect to the subject matter of claim 1. As discussed below, the amount of uncertainty and experimentation is substantially less than the Office asserts. Moreover, the Office is not correct in implying that the disclosure consists of “a mere germ of an idea.” The present disclosure provides ample description of how to make and use the claimed invention together with working examples of representative species of the claimed invention.

By following the description and examples of the specification there would not be undue experimentation required for a skilled person to isolate the intron of the 5'-non-translated region from any plant H3.3 histone genes in addition to the representative *Arabidopsis* H3.3 histone genes. One reason is that H3.3 histone genes constitute a very conserved histone family in terms of amino acid sequences, and this is even more true among

the H3.3 histone genes from plants (see Chaubet et al., *supra*). For example, BLASTp comparisons show that the histone H3.3 from rice (*Oryza*) and vine (*Vitis*) share 100% identity with the one of *Arabidopsis* from which the intron disclosed in the Examples have been isolated. (Attached as Exhibit A). Considering the sequence identity, there would be no undue experimentation for a skilled person to clone genes encoding H3.3 histone from plants other than *Arabidopsis* by using well-known molecular biology and cloning methods (*e.g.* using probes to screen genomic or cDNA libraries for the conserved sequences).

Further, the disclosure of the specification teaches that the recited intron is the intron of the 5'-non-translated region of the histone gene. Given the teaching of the specification, and the conserved sequences of H3.3 histone genes, a skilled person would have no undue burden in identifying the 5'-non-translated region of a cloned plant histone gene. The 5'-non-translated region is known to be the region located upstream the ATG codon of a gene. A single large intron is known to be located in this region in histone H3.3 genes. *See*, Chaubet et al., *supra*.

Finally, there would again be no undue burden for a skilled person to identify the said intron within the 5'-non-translated region using the classical consensus 5' and 3' splice junctions. *See e.g.*, Sinibaldi, *supra*. Such consensus sequences are present in the intron of the 5'-non-translated region of the *Arabidopsis* H3.3 histone intron disclosed in SEQ ID NOS: 6 and 7 of the application (*See also* Chaubet *et al.*, *supra*, page 570, left column, lines 31-32).

In view of at least the foregoing, the Office has failed to show that the disclosure and examples of the present specification are not adequate to enable one skilled in the art to make and use the claimed invention commensurate with the scope of the claims. Withdrawal of the

rejection under 35 U.S.C. § 112, specifically the first paragraph enablement requirement, is appropriate and is respectfully requested

Rejection under the judicially created doctrine of obviousness-type double patenting

Claim 1 has been rejected under the judicially created doctrine of obviousness-type double patent as allegedly being unpatentable over claims 1 and 2 of United States Patent No. 6,338,961. A terminal disclaimer is submitted herewith, thereby obviating the alleged basis of the rejection. Withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

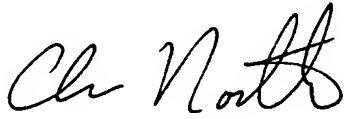
In the event that there are any questions relating to this Amendment and Reply, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Respectfully submitted,

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